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EXAMINER

QIAN, CELINE X

ART UNIT PAPER NUMBER

1636

DATE MAILED: 12/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/030,658

Applicant(s)

YAMAMURA ET AL.

Examiner

Celine X Qian Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 13-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8, 11 and 12 is/are rejected.
- 7) ☒ Claim(s) 9 and 10 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 January 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 1/11/02, 4/11/02, 7/15/02, 6/09/04
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

**DETAILED ACTION**

Claims 1-18 are pending in the application.

***Election/Restrictions***

Applicant's election with traverse of Group I and species g) in the reply filed on 10/7/04 is acknowledged. The traversal is on the ground(s) that the species of the trap vector share a significant structural element, loxP sequence. Applicants assert that all the trap vectors have the same utility. Therefore, the unity of invention is present. This is not found persuasive because the claimed species do not share a significant structural element as defined by MPEP Annex B. Since the structure of a significant portion of the vector, including SA, SD, M and PV, is unknown, the vectors are not considered to share a significant structure element. Even though the sequence of loxP site is known, however, it is only a small portion of the claimed vector (34 base pair). As such, it cannot be considered as a significant structural element. Further, the unity of the invention is not based solely on the utility of the composition. Therefore, the claimed species lack unity for same reasons discussed in the restriction requirement and above.

The requirement is still deemed proper and is therefore made FINAL.

Accordingly, claims 13-18 are withdrawn from consideration for being directed to non-elected subject matter. Claims 1-12 are currently under examination.

***Claim Objections***

Claims 9 and 10 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot reference to two sets of claims to different features. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7, 8, 11 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 7, 8 and 12, the recitation of "puro represents" renders the claim indefinite because it is unclear what puro represents. As such, the metes and bounds of the claim cannot be established.

Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: how to trap the gene. Simply introducing the trap vector into embryonic stem cells would not result in a gene to be trapped. Applicant is advised to amend the claims to include essential steps so that the method is complete.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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This rejection is based on a 35 USC 102(a) date availability since the foreign priority document has not been perfected. A certified English translation of the foreign priority document would remove the availability of the reference under 102(a) if all the claimed subject matter is disclosed in the foreign priority document.

Claims 1-3, 11 and 12 rejected under 35 U.S.C. 102(a) as being anticipated by Araki et al (see IDS).

The claims are drawn to a trap vector comprising a mutant loxP, such as lox71 (see Figure1A and 2A). The claims are further drawn to a method of gene trapping by introducing the trap vector into ES cells, and ES cells into which the trap vector is introduced.

Araki et al. disclose gene trap vectors comprising mutant loxP, loxP and lox66. Araki et al. further disclose a method of gene trapping by introducing the trap vector into ES cells, and ES cells into which the trap vector is introduced. Therefore, Araki et al. disclose the instantly claimed invention.

Claims 1-3, 11 and 12 are rejected under 35 U.S.C. 102(e) as being anticipated by Ong et al. (US 6,777,235).

Ong et al. disclose a trap vector comprising mutant loxP, lox71 (see col.14, lines 54-55), is introduced into ES cell. Therefore, Ong et al. disclose the instantly claimed inventions.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

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the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 4-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ong et al.

The teaching of Ong is discussed above. Ong et al. further teach that heterologous DNA would then be introduced into trapped events by co-electroporation of a transgene as a circular plasmid containing a single mutant lox66 site with CRE expression cassette. However, Ong et al. does not teach a trap vector comprising a mutant loxP, lox66.

It would have been obvious to one of ordinary skill in the art to make a trap vector comprising lox66 based on the teaching of Ong et al. Ong et al. already teach a trap vector comprising a mutant lox71, which will recombine with lox66 in the presence of Cre. As such, using trap vector having lox66 or lox71 would be interchangeable and routine experimentation in the method taught by Ong et al. The level of skill in the art is high. Absent evidence from the contrary, one of ordinary skill in the art would have

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reasonable expectation to replace lox71 with lox66 in the trap vector taught by Ong et al. Therefore, the invention would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X Qian Ph.D. whose telephone number is 571-272-0777. The examiner can normally be reached on 9:30-6:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CELIAN QIAN  
PATENT EXAMINER



Celine X Qian Ph.D.  
Examiner  
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